

Guidance on Assent of Minor Form and Process Preparation

In accordance with 45 CFR 46.402(b), assent is defined as a child's affirmative agreement to participate in research. The child must actively show his or her willingness to participate in the research rather than just complying with directions to participate and not resisting in any way. Mere failure to object, absent affirmative agreement, should not be construed as assent. Assent is obtained from each child who participates in research unless they are not capable of understanding what is being asked of them.

The purposes of assent are: (1) information exchange between the research team and the child; (2) enhances decision making process between the parents and the child; and (3) granting child ability to exercise dissent.

When creating the process, the following components must be considered: ages, maturity, psychological state of the children involved and the nature of the proposed research.

Assent Process Protocol Description

The information detailed in the protocol will provide a base for the information that will be included in the assent document. If the information is not detailed in the protocol the IRB will not have been provided with accurate information regarding the assent process or the detail that should be included in the process or the document. Hence, it is important to consider the categories in this section because investigators have a legal and ethical obligation to ensure that prospective subjects/subjects' representatives have sufficient knowledge and comprehension of the elements of process and the study. The information presented to subjects must be clear in order to enable subjects to make an informed and enlightened decision whether or not to participate

1. **Method of Subject Identification and Recruitment.** Describe the method(s) that will be employed in the identification and recruitment of prospective subjects. Note: The identification and recruitment of subjects must protect privacy and be free of undue influence. Recruitment of an investigator's own staff, employees and patients may be considered potentially coercive and steps should be taken to minimize undue influence. These should be outlined in the protocol.
2. **Process of Assent.** Describe who will obtain assent, how the assent process will be structured, and what will be done to ensure the process is conducive to rational and thoughtful decision making by the child/subject. Describe the use of additional tools that will be used to assist children in understanding the research e.g such as plush toys, pictures, dolls, etc. Describe how children will be made to feel comfortable. Describe how questions will be answered. If necessary to use 'Auditor/Witness' and/or translator, these roles would be described in this section.
3. **Subject Capacity.** Describe the age of the children, their ability to provide assent and how their individual capacity to understand will be assessed in this project. Determination of a child's ability to assent should be based on the following components: (1) the nature of the proposed research; (2) age, (3) maturity level, and (4) psychological capability. The IRB is charged by the

Federal Regulations to ensure these components are taken into account during the review of the proposed project.

For research activities involving adolescents whose capacity to understand resembles that of adults, the assent procedure should likewise include information similar to what would be provided for informed consent by adults or for parental permission. For children whose age and maturity limits their ability to fully comprehend the nature of the research project but who are still capable of being consulted about participation, it may be appropriate to focus on conveying an accurate picture of what the participation in the research is likely to be (for example, what the experience will be, how long it will take, whether it might involve any pain or discomfort. In studies where an investigative new drug is involved is the only suitable treatment for the child and there is no other treatment, assent can be waived. As stated in 45 CFR 46 Subpart D; when the IRB determines that assent is required, it shall also determine whether and how assent must be documented in the study. The IRB relies on the information provided by the researcher when making this determination.

4. **Subject/Representative Comprehension.** In this section, describe how it will be determined that the subject understood the information presented. This section should clearly document that the investigator has an adequate plan in place to assure an acceptable level of comprehension before assent is obtained. This section should also include a specific plan to assess comprehension during assent (the subject's agreement).
5. **Debriefing Procedures.** In psychological studies where any information will be purposely withheld from the subject, state the information to be withheld, justify this non-disclosure and describe the post-study debriefing of the subject.
6. **Documentation of Assent.** The PI is responsible for ensuring that assent is obtained and documented for all subjects, when appropriate. If not already addressed in item two above (Process of Assent) specifically describe how assent will be documented and how/where documentation will be stored.
7. **Payment for Participation.** Describe any reimbursements or payments such as cash payments, coupons and gift certificates that the subjects will receive for participation. List what must be completed by the subject to obtain the compensation. The amount must be justified and not constitute undue inducement of the subject to participate in the research or to continue beyond a point that they would have otherwise withdrawn. Note: The IRB requires a prorated system for financial payments. This means that payments are accrued as the study progresses and that subjects do not have to complete the entire study to be eligible to receive a payment. This is to protect the subject's right to withdraw without penalty.

The National Cancer Institute suggests like the informed consent process, the assent process is intended to be an ongoing, interactive conversation between the research team and the child or young adult. The process is not about getting the young person "to sign on the dotted line"; rather, it is about making sure they understand the study and what it means to participate. By engaging young people in understanding the research project, health care providers and young patients may

become "partners" in the project. Children are likely to feel more in control and more involved in the trial as a result.

The assent process should reflect a reasonable effort to enable a child to understand, to the degree they are capable, what their participation in research would involve. More than one method for obtaining assent may be used when participants represent a wide range of ages. Verbal assent is appropriate for children who are younger than the age of 7. For children approximately age seven and older, assent is sought either verbally or in a simple form written at the second or third grade reading level. Children 14 and older may understand the language presented in the consent form for parents. If so, they may sign the consent form along with the parent or guardian. Forms for parents and older children need to be written at the sixth to eighth grade reading level. The IRB approves the text of each assent statement, whether verbal or written.

Tips for Preparing an Assent Form Document and Process

- (1) Keep language simple.
- (2) Use larger type and pictures for younger age groups such as 7-11 years. Try to limit to one page, if possible.
- (3) Ensure the information in the form matches what will be verbally exchanged with the child during the assent process.
- (4) Ensure study procedures that are not part of the child's regular care are highlighted.
- (5) Any information that can affect a child's decision to take part should be included, e.g., stating that the study involves approaching the child's teacher about how the individual acts in school, or inviting playmates to take part in the study.
- (6) Take your time. The consent process may take more than one visit to complete. Ensure all questions are addressed that are asked and encourage the child to ask questions.
- (7) Involve the family in the process. Ensure the child is comfortable as much as he or she can be in the situation.
- (8) Think outside the box when creating the assent process. A video tape of procedures to be completed or a power point may assist the child in understanding more of what is happening. The use of dolls or plush toys may assist in explaining procedures.
- (9) During the review process, the IRB must ensure that technical and scientific terms are adequately explained or that common terms are used instead. The IRB needs to ensure that the document properly translates complex scientific concepts into simple concepts that the typical subject can read and comprehend. Using lay language and common terms will reduce the request for modifications.

Although not prohibited by regulations, use of the wording, "I understand..." in assent documents may be inappropriate as many prospective subjects will not

"understand" the scientific and medical significance of all the statements. Second person writing style helps to communicate that there is a choice to be made by the prospective subject. Use of first person may be interpreted as presumption of subject agreement, i.e., the subject has no choice. Also, the tone of the first person "I understand" style seems to misplace emphasis on legal statements rather than on explanatory wording enhancing the subject's comprehension.

Subjects are not in a position to judge whether the information provided is complete. Subjects may certify that they understand the statements in the consent document and are satisfied with the explanation provided by the consent process (e.g., "I understand the statements in this informed consent document). They should not be required to certify completeness of disclosure (e.g., "This study has been fully explained to me," or, "I fully understand the study.")

For phase I drug studies, the board usually requires assent from children because most phase I studies are not designed to be of benefit to the participants. Phase I study objectives usually include determination of maximum tolerated drug dose, ascertaining toxicities and learning about the pharmacokinetics of the drug being evaluated. Federal Regulations state that if the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children **and** is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with the waiver of consent regulations.

Some Additional Thoughts:

In case where a child may lack the capacity to assent to participate, assent may be waived for that child. This type of waiver may be used on a case by case basis when the researcher believes that the age, maturity level, and psychological state of the particular child would not yield adequate assent. This should be used sparingly and when possible in consultation with the IRB. The researcher should always report such instances to the IRB immediately following the consent/assent process.

Researchers should note however, that since assent of minor is based upon the basic ethical principle -respect for person - the researcher may not ask for assent only from compliant subjects, or depend on parental permission. If assent is requested of and not granted by a child, the child's refusal to participate in the research is binding.